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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,368	01/14/2004	Secondo Dottori	725.1108.1039	2368

20311 7590 12/15/2009

LUCAS & MERCANTI, LLP
475 PARK AVENUE SOUTH
15TH FLOOR
NEW YORK, NY 10016

EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
12/15/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@lmiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/756,368	DOTTORI ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

New claims 67-69 are pending and are considered on the merits.

Claim Rejections - 35 USC § 112

Claims 67-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicant has amended the claims to recite "may be effectively stored for up to 8 days". There is no support for this recitation in the generic portion of the specification, the original claims, or in the examples which do not correspond to the breadth of the claim. The only support is in an example on page 31 where the addition of 5 mM L-carnitine to leukoreduced platelet concentrates and subsequent storage @ 22°C for 3, 6, 7 and/or 8 days is shown. This is far narrower support than is now in the claimed method. First, the concentration of L-carnitine is 5mM, which is not in the claimed method. Second, only L-carnitine is added, not salts or esters or salts of esters. Third, the storage temperature is 22°C in the example, while there is no limitation to the storage temperature in the claim.

Insertion of the limitation explained above has no support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limitation which would show possession of the concept. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Thus, these insertions are considered to be the insertion of new matter for the above reasons.

Please see *Gentry Gallery v. Berkline* 45 U.S.P.Q.2d 1498 for a discussion related to broadening the claimed invention without support in the as-filed specification. **Please see *PurduePharma v. Faulding* 56 U.S.P.Q.2d 1481 for a discussion related to a failure to describe a claimed generic concept in the narrative portion of the specification, but rather basing support on limitations in examples.**

INDEFINITE

Claims 67- 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 67 recites "effectively stored". However, what constitutes an effective storage is unclear because there is no objective definition a parameter which may be compared to determine an effective or ineffective storage.

L-carnitine and salts thereof are discrete compounds. They are not and cannot be esters. Carnitine not a generic term for the ester compounds listed in claim 69. Thus, claim 69 does not further limit the independent claim. Also, "butyril" is a misspelling in claim 69.

Claim Rejections - 35 USC § 103

Claims 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney *et al.* [AW] in combination with US 5,747,536 [AA] and Ogawa *et al.* [U] and Tegos *et al.*[V].

The claims are directed to a method comprising:

leuko-reducing a platelet concentrate,

adding L-carnitine or an ester of carnitine or salts thereof to a platelet concentrate and,

suspending the platelet concentrate in the mixture.

The claim also has a phrase which is not an active step, but merely a wherein phrase which states that the platelet suspension may be effectively stored for up to 8 days. This is merely a desired result and consequently is given little patentable weight.

The intent of the claimed methods is the suppression of bacterial growth in the platelet concentrate.

The references are relied upon as discussed below.

Sweeney *et al.* disclose a method of adding L-carnitine or acetyl-carnitine (5mM) to platelet concentrates and agitating the mixture. This is said to reduce glycolysis in the platelet mixture. Glycolysis impairs the quality of the platelet product.

Tegos *et al.* teach that glycolytic enzymes are present in isolated platelets.

Ogawa *et al.* teach the advantages of leukodepleting platelet products with regard to prevention of adverse reactions to PC transfusion and that leukodepleted platelets still possess glycolytic activity.

US 5,747,536 discloses that esters of carnitine other than acetyl ester are known.

The primary reference lacks the disclosure of leukodepleting the platelet concentrate and use of the homologous derivatives of acetyl-carnitine.

The substitution of other esters of carnitine such as butyryl, valeryl, propionyl, isobutyryl for the acetyl ester of carnitine in the method of Sweeney *et al.* would have been obvious when US 5,747,536 was taken with Sweeney *et al.* because US 5,747,536 lists various esters of carnitine and also further

discloses the addition of carnitine or its derivatives to platelet concentrates. In the absence of evidence to the contrary, the salts and esters of L-carnitine would reasonably be expected to have a similar activity to L-carnitine or acetylcarnitine because these are simple homologs which may be reasonably expected to have similar properties and activities in the absence of evidence to the contrary.

The substitution of a leukodepleted platelet concentrate for the platelet concentrate of the primary reference would have been obvious because both a nonleukodepleted platelet concentrate and a leukodepleted platelet concentrate comprise platelets, and platelets are known to possess the glycolytic enzymes, see Tegos *et al.* which result in glycolysis during storage. Therefore, even if the leukocytes are removed for advantages known in the art, see Ogawa *et al.*, glycolysis in the preparation would still be expected to occur because platelets perform glycolysis by virtue of having glycolytic enzymes. Thus, the addition of L-carnitine, salts or esters thereof, to a leukodepleted platelet concentrate would be expected to reduce the glycolysis in the platelets and to maintain platelet quality as taught by Sweeney *et al.*.

Although the applicant has recognized another advantage which would flow naturally from following the suggestions of the prior art, this fact cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Although the intent of applicant's method is different from the intent of the disclosed method, the active step of adding carnitine or an ester of carnitine in the same concentration is the same. Thus, the results of the method, suppression of bacterial growth, would reasonably be assumed to be the same as the result claimed.

It is not relevant to the analysis of the claimed method that the reference makes no mention of suppressing bacterial growth. Discovery of a new benefit for an old process does not render the old process patentable. *In re* Woodruff,

919 F. 2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Merely because the reference did not have one of applicant's purposes in mind when the (drug was administered) does not alter the drug's physiological activity. In the context of an anticipation rejection, the Federal Circuit stated, "Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results." Mehl/Biophile Int'l Corp. v. Milgraum, 192 F. 3d 1362, 1366, 52 USPQ2d 1303, 1307 (Fed. Cir. 1999).

See also *In re* Cruciferous Sprout 64 USPQ2d 1202 Fed. Circuit.

The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed.Cir. 2006) (motivation question arises in the context of the general problem confronting the inventor rather than the specific problem solved by the invention); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1323, 76 USPQ2d 1662,1685 (Fed. Cir. 2005) ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings."); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) (discussed below); *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991). MPEP 2144IV.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicant's arguments filed 11/25/09 have been fully considered but they are not persuasive.

Applicant argues that the results on page 31 demonstrate results which are far superior to those described by Sweeney et al., which is storage for up to 8 days. The same compound is added in the same concentration to a platelet composition. Just because Sweeney *et al.* terminates the experiment on day 5, does not meant that the results demonstrated in the instant specification are better or unexpected.

Even if applicant were to limit the claimed method to adding 5mM L-carnitine and storing the platelet concentrate @ 22°C for 7-8 days, the active step of adding 5mM L-carnitine or acetyl-L-carnitine to platelet concentrates is exactly what the prior art teaches. One cannot overcome prior art by performing the same or an exceedingly similar step of adding the same compound in the same concentration to the same platelets or obvious variants thereof absent direct comparison, in a clear, convincing, scientifically correct manner with the prior art method to show that whatever variation may exist is not obvious.

The length of time of storage of a platelet concentrate would also be obvious because there is no evidence that the platelets of Sweeney *et al.* could not be stored for up to 8 days since the same concentration of the same compound is added to platelets. The fact that applicants extended their period of storage to 8 days, with or without having a storing step in the claimed method, is legally obvious in the absence of a direct comparison with the method of Sweeney *et al.* using the platelet concentrate of Sweeney *et al.* AND a claim commensurate in scope with such a showing.

Applicant argues that Cavazza (US '536) is not related to the instant invention and is not analogous art. Please see the statement of why the reference is relied upon. US 5,747,536 discloses that esters of carnitine other than acetyl ester are known and is relied upon for that disclosure. A known

compound is a known compound. Analogous compounds, that is compounds having homologous structures are expected to have similar activities, *i.e.* propionyl, butyryl, valeryl esters of L-carnitine, are homologous chemical structures to the acetyl ester of carnitine used in the reference. They are not novel compounds as demonstrated by US '536, therefore, the substitution of any ester of carnitine for acetyl carnitine in a known method is *prima facie* obvious in the absence of evidence to the contrary.

Applicant argues that Ogawa merely states that prestorage leukocyte filtration reduces the severity of post-transfusion side effects. This is precisely why it is cited. See the statement of the teaching of the reference which is relied upon, above. The reference provides motivation for the substitution of a platelet composition which is leucocyte depleted for a non-leucocyte depleted platelet composition in the method of Sweeney *et al.*. One of ordinary skill would be motivated to perform this substitution because of the advantages known in the transfusion field when leucocytes are reduced in platelet concentrates as taught by Ogawa *et al..*

Applicant argues that the storage time are different in the various references. While this may be true, the step of storing is not an active step in the claimed method, and even if it were, one of skill in the art may store for as long as wished in the absence of evidence to the contrary.

Applicant argues that a platelet concentrate that can be stored for 8 days is an unexpected improvement. However, applicant does not compare the process of the cited primary reference with his process, therefore, the arguments is unpersuasive of error in the construction and application of the rejection.

The arguments are not persuasive because the examiner considers the above rejection to disclose all of the elements of the claimed process, *i.e.* all of the active process steps and the product being acted upon AS CLAIMED and

the elements are logically and reasonably linked together, which provides motivation for the combination of references.

Merely because applicant has discovered another effect of a method that is obvious in view of the cited prior art, does not make that method patentable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/
Primary Examiner, Art Unit 1651